IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	**PUBLIC VERSION** C.A. No. 21-691 (GBW) [redacted]
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	 C.A. No. 21-1138 (GBW) [redacted]
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	 C.A. No. 21-1594 (GBW) [redacted]

JOINT SECOND SUPPLEMENTAL CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

I. INTRODUCTION

A. Jazz's Opening Introduction

The parties dispute whether Jazz's method-of-treatment claims[1] require efficacy. As explained below, the Court should not import any efficacy limitation into the claims.

B. Avadel's Answering Introduction

During the initial *Markman* proceedings, Jazz represented, under the heading "Once-Nightly Formulations Discovered and Claimed in the Patents-in-Suit," that the claims of the patents-in-suit involve "formulations comprised of both immediate release drug particles (to help the patient fall asleep right away) and sustained/controlled/modified-release particles (to help the patient stay asleep throughout the night), as well as methods of using those formulations for the treatment of EDS and cataplexy." D.I. 132 at 3. Against that backdrop, Jazz now remarkably asserts that various portions of the subject claims have no substantive import.

Jazz's position that the phrases at issue are "not limiting" or alternatively do not require an efficacious purpose (*infra* at 1) cannot be squared with the plain language of the claims, applicable case law, or Jazz's prior representations to this Court. Avadel's proposed constructions should be adopted.

C. Jazz's Reply Introduction

In its opposition ("[*infra/supra*] at __"), Avadel concedes for the first time that there is no efficacy requirement in the asserted MoT Claims (acknowledging that "treating" does not require "a certainty of outcome" and that Avadel's construction "does not require 'an improvement'"). *Infra* at 11-12. This is a far, but welcome, departure from Avadel's pre-briefing correspondence

[1] Claims 1-8 and 10-11 of U.S. Patent No. 10,959,956 (Ex. 1), claims 1-6 and 8-15 of U.S. Patent No. 10,966,931 (Ex. 2) (together, "SR MoT Claims"), and claims 1-3, 5, 7, 10-12, 14, 16-18 of U.S. Patent No. 11,077,079 (Ex. 3) ("'079 MoT Claims").

and certain of its expert reports where Avadel previously claimed that Jazz was wrong that "the term 'treating' does not include a safety or efficacy requirement" (Ex. 11 at 2) and "wrong that the 'single daily dose' limitation . . . does not impose any safety or efficacy requirement" (Ex. 12 at 5).[2,3] Based on Avadel's and its experts' statements, Jazz previously understood the crux of the dispute to be whether there was an "efficacy requirement" in the claims. But, regardless of whether the preambles are limiting (as explained below, they are not), ***the parties now agree*** that the preambles and "single daily dose" limitation do not support reading a non-existent efficacy requirement into the MoT Claims.[4] For the "wherein" clause in claims 5 and 14 of the '079 patent, Avadel is also wrong that "promotes" should be construed to mean the same thing as "induces." *Infra* at 28. "Promotes" and "Induces" are plain English words, and as reflected in the only dictionary definitions in the record, "promotes" means an aspirational or intended result, while "induces" means something that actually causes an outcome to happen. Jazz's proposals should, therefore, be adopted. *See, e.g.*, Exs. 8-10.

D. Avadel's Sur-Reply Introduction

Avadel has not changed its position on the claims' meaning. Avadel has consistently argued that the preambles are limiting and require an efficacious purpose to treat. A "single daily dose" similarly requires that the single dose is intended to be effective (even if in some cases it is

[2] As noted in Jazz's opening portion, and not disputed by Avadel in its opposition, the parties agree that the claims do not require safety. *Infra* at 3, n.5.

[3] *See also, e.g.*, Ex. 13 at ¶ 166 (Avadel expert opinion that "[Jazz's expert] argues that 'the Sustained Release Asserted Claims do not require efficacy'. . . . I disagree with [Jazz's expert's] views."); *id.* at ¶ 279 ("[A] POSA would have understood the claim language 'administering a single daily dose to the patient' to reflect a requirement that the single dose administered be considered safe and effective . . . .").

[4] Indeed, Avadel is now arguing for an "efficacious purpose" construction for the "single daily dose" limitation, not that it is "effective to treat" the disorders recited in the '079 patent's preambles, which is the position Avadel took in pre-briefing correspondence. *See* Ex. 12 at 5.

not). Indeed, Jazz argued during prosecution that "[i]n contrast" with the prior art "the presently-claimed methods provide ***therapeutic effectiveness*** through once-daily administration…." Ex. G ('079 patent File History, May 20, 2021 Remarks) at 12. The "wherein" clauses of claims 5 and 14 of the '079 patent likewise have meaning; the dispute is not over the words "promotes" and "induces," which carry their ordinary meaning.

II. DISPUTED CONSTRUCTIONS

A. The Sustained Release Method of Treatment Claims

1. "A method for treating cataplexy or excessive daytime sleepiness associated with narcolepsy in a patient in need thereof"

Claim Term	Jazz's Proposal	Avadel's Proposal
"A method for treating cataplexy or excessive daytime sleepiness associated with narcolepsy in a patient in need thereof"	not limiting; if limiting, then the plain and ordinary meaning of "treating": an attempt to cause an improvement, without any requirement of efficacy or safety[5]	A limiting statement of efficacious purpose

a) Jazz's Opening Position

Avadel relies on the preamble in an attempt to import its proposed efficacy limitation.

Claims: "Generally, the preamble does not limit the claims." *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). The Federal Circuit recently refused to read efficacy and safety limitations into the preamble "treating pulmonary hypertension." In *United Therapeutics Corporation v. Liquidia Technologies*, the Federal Circuit found that "[q]uestions of safety and efficacy in patent law have long fallen under the purview of the FDA," and "decline[d]

[5] Avadel previously asserted that the MoT Claims required safety but did not advance that position in *Markman* exchanges. Thus, the parties agree that safety is not required.

to insert the FDA's responsibilities into claims by importing requirements where they do not recite such limitations."[6] 74 F.4th 1360, 1369 (Fed. Cir. 2023).

Recitation of "a patient in need thereof" ***within the preamble*** does not dictate that the preamble is limiting. Instead, courts find "[a] method for treating" language limiting when the "in need thereof" language appears in the ***body of the claim***, not the preamble. *See, e.g.*, *Rapoport v. Dement*, 254 F.3d 1053, 1059 (Fed. Cir. 2001); *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1330, 1333 (Fed. Cir. 2003). To the extent that Avadel argues that "a patient in need thereof" within the preamble provides antecedent basis for "the patient" in the body of Jazz's claims to whom the compound is "deliver[ed]," that still does not dictate that the "method for treating" language is limiting. Instead, the Federal Circuit has held that a "court err[s] in determining that it ha[s] to construe the entire preamble if it construe[s] a portion of it." *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323 (Fed. Cir. 2015). "That [one] phrase in the preamble . . . provides a necessary structure for claim 1 does not necessarily convert the entire preamble into a limitation, particularly one that only states the intended use of the invention." *Id.*

The phrase "[a] method for treating" in the SR MoT Claims' preamble "does not provide an antecedent basis for any of the claims. Rather, it is language stating a purpose or intended use and employs the standard pattern of such language: the words 'a method for a purpose or intended use comprising,' followed by the body of the claim, in which the claim limitations describing the invention are recited." *Id.* at 1323-24. The bodies of the SR MoT Claims then require that formulations with certain structural requirements and deionized water dissolution profiles be "deliver[ed]" to the patient—nothing more.

---

[6] In *United Therapeutics*, the district court held "'***therapeutically effective*** single dose' to be a dose given in a single treatment session that causes an improvement in a patient's hemodynamics." *Id.* at 1369 (emphasis added). Jazz's claims do not include a "therapeutically effective" limitation.

If the Court holds "[a] method for treating" is limiting, then the plain and ordinary meaning of "treating" should apply, which is an attempt to cause an improvement, without any requirement of efficacy or safety. *See Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001) (no safety or efficacy required where the claimed method steps "are performed in the same way regardless whether or not the patient experiences a [certain measure of efficacy]"); *Novartis Pharms. Corp. v. Actavis, Inc.*, No. 12-366, 2013 WL 6142747, at *11 (D. Del. Nov. 21, 2013) (plain meaning of "treating" is "to ***attempt*** to cause a therapeutic improvement, without necessarily having assurance of what the outcome will be") (emphasis in original); *Chiesi USA Inc. v. MSN Pharms. Inc.*, No. 19-18564, 2021 WL 4843806, at *4 (D.N.J. Oct. 18, 2021) (plain meaning of "treating" does not require that the method must "cure or heal" the condition); *Celgene Corp. v. Hetero Labs.*, No. 17-3387, 2020 WL 3249117, at *5-6 (D.N.J. June 16, 2020) (plain meaning of "treating" does not require safety or efficacy); *In re Ciprodex*, No. 15-5756, 2017 WL 2784410, at *11 (D.N.J. June 27, 2017) (plain meaning of "treating a human patient" is "attempting to cause a therapeutic improvement in a human patient"); *Schering Corp. v. Mylan Pharms., Inc.*, No. 09-6383, 2011 WL 2446563, at *5 (D.N.J. June 15, 2011) (noting that "[t]o treat a disease does not imply that the progression of the disease will actually be slowed, arrested or reversed").

Specification: The specification further reinforces that there is no efficacy requirement. The specification consistently uses the plain meaning of "treatment"—i.e., not requiring efficacy. *See, e.g.*, Ex. 1 at 2:57-61, 3:56-4:3, 24:19-26:57. Further, the specification states that, "[i]n ***certain embodiments***, the controlled release compositions described herein are formulated as unit dosage forms that deliver ***therapeutically effective amounts*** of drug. . . ." Ex. 1 at 5:47-49 (emphasis added); *see also id.* 5:47-6:3. The words "therapeutically effective amounts" do not appear in the claims. Rather, as noted above, the claims only require "delivering" the claimed

formulation. This intrinsic evidence further distinguishes the SR MoT Claims from those that require efficacy. *See, e.g.*, *Eli Lilly & Co. v. Teva Pharms. Int'l*, 8 F.4th 1331, 1342 (Fed. Cir. 2021) (claims required efficacy because "each independent claim [included] a step of administering an 'effective amount' of an anti-CGRP antibody"); *United Therapeutics*, 74 F.4th 1360, at 1369 ("'[T]herapeutically effective single dose' [is] a dose given in a single treatment session that causes an improvement in a patient's hemodynamics."); *Celgene*, 2020 WL 3249117, at *6 (no efficacy required where the specification used "the words 'treat,' 'treating,' or 'treatment' . . . without an efficacy requirement").

File Histories: The file histories do not support Avadel's attempted limitation. In particular, Avadel cannot show that there was "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). Instead, all Avadel has cited is the Examiner distinguishing the claims from the prior art (Conte) based on the "sustained release formulation as claimed, wherein the composition comprises a methacrylic acid-methyl methacrylate copolymer . . . [and] [t]he claimed copolymer coating, unlike the Conte polymer, is water soluble only at or above a certain pH, such that the Conte polymer will possess a different release profile." *See* Exs. 4-5. The preamble was never relied upon.

b) Avadel's Answering Position

The parties first dispute whether the preambles of the Sustained Release method of treatment claims 1-8 and 10-11 of the '956 patent and claims 1-6 and 8-15 of the '931 patent mean anything and second, if they do, whether they require an efficacious purpose. The answer to both questions is yes. The claim language is enough to show this, consistent with general principles of claim construction and this Court's recent holding in *Novartis Pharms. Corp. v. HEC Pharm Co.*, C.A. 20-133-GBW, 2023 WL 2810062, at *2 (D. Del. Apr. 6, 2023) (Williams, J.) (*Novartis I*).

(1) The Preambles are Limiting

Federal Circuit law dictates that the preambles are substantive limitations. First, the phrase "[a] method for treating . . . a patient in need thereof" provides the antecedent basis for "the patient" discussed throughout the claims. Ex. A ('956 patent) at claims 1, 11, and 12; Ex. B ('931 patent) at claim 1. The Federal Circuit has "repeatedly held a preamble limiting when it serves as antecedent basis for a term appearing in the body of a claim." *In re Fought*, 941 F.3d 1175, 1178 (Fed. Cir. 2019). Here, the preambles refer to "[a] method for treating . . . a patient in need thereof," and consistently rely on that statement to refer back to "the patient." Ex. A at claims 1, 11, and 12; Ex. B at claim 1. Courts routinely deem such language as limiting on these grounds. *See Eli Lilly and Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1343 (Fed. Cir. 2021) (finding a preamble limiting where it provided "antecedent basis for at least one later claim term in the independent claims, namely, the term 'administering to ***the individual***,' which refers back to the preamble term 'treating ... in ***an individual***'").

Second, the preambles are limiting because they are "'necessary to give life, meaning, and vitality' to the claim[s]." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). The claims refer to a patient "in need," which describes the objective of the method. *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) ("the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone 'in need.' . . . [T]he claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose.") (discussing *Rapoport v. Dement*, 254 F.3d

1053, 1059 (Fed. Cir. 2001)).[7] Thus, the preambles are limiting both because they provide antecedent basis and they give life and meaning to the purpose of the method.

Perhaps the clearest evidence is Jazz's own Final Infringement Contentions, in which Jazz repeatedly treated the preambles as a limitation. *See, e.g.*, Ex. C (excerpts of Plaintiff's Final Infringement Contentions) at 108 (alleging without qualification that "Avadel's NDA Product will literally meet [the preamble's] limitation" for claim 1 of the '956 patent because it will "treat cataplexy or excessive daytime sleepiness associated with narcolepsy in a patient in need thereof"); 178 (similar); 207 (similar); and 214 (similar). Jazz unambiguously asserted that the limitations were substantive requirements satisfied by LUMRYZ™. It cannot retreat from that position in an attempt to preserve the validity of the claims. *White v. Dunbar*, 119 U.S. 47, 51 (1886) (noting that a patent may not "like a nose of wax" be "turned and twisted in any direction" and finding that "[t]he claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.").

Jazz asserts that merely because one "phrase in the preamble . . . provides a necessary structure for claim 1 does not necessarily convert the entire preamble into a limitation, particularly one that only states the intended use of the invention." *Supra* at 4 (quoting *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323 (Fed. Cir. 2015)) (alteration in original). However, *TomTom* is inapposite. It involved a preamble reciting a method for "generating and updating data ***for use in***

[7] Jazz contends that *Jansen* is inapposite because "courts find '[a] method for treating' language limiting when the 'in need thereof' language appears in the ***body of the claim***, not the preamble." *Supra* at 4. In fact, the Federal Circuit explicitly rejected that argument in *Jansen*, finding that what matters is that so long as the "'treating or preventing' phrase" and the "to a human in need thereof" phrase are each "a part of the claim" (i.e., not just in the body), "they compel" a limiting construction. *Jansen*, 342 F.3d at 1333.

a destination tracking system of at least one mobile unit." 790 F.3d at 1323 (quoting '836 patent col. 17 ll. 36-37). The case law concerning methods of using pharmaceuticals to treat a patient in need uniformly construe them to be limiting as set forth above.[8]

Moreover, the district court in *TomTom* "determined that two phrases found in the preamble . . . must both be construed" and "construed the[] two preamble phrases separately." *Id.* The Federal Circuit held that the district court "erred in determining that it had to construe the entire preamble if it construed a portion of it." *Id.* That is not the situation here, where both parties have agreed that the whole preamble must be construed as a single term.

(2) The Preambles Require an Efficacious Purpose

Avadel respectfully submits that the case law undermines Jazz's assertion that the claim terms are "not limiting." The same is true as to the corollary issue of efficacious purpose. The claims recite "a method for treating . . . a patient in need thereof." The Federal Circuit has recognized that such language requires some level of efficacious purpose. *Manning v. Paradis*, 296 F.3d 1098, 1103 (Fed. Cir. 2002) ("The plain meaning of the word 'treat' requires that the invention of the count is used to seek or to achieve a therapeutic effect on the subject, rather than simply providing oxygen to the subject's heart."); *In re 318 Patent Infringement Litig.*, 578 F. Supp. 2d 711, 725 (D. Del. 2008) (construing a "method of treating" to mean "[a] method of alleviating the symptoms or deferring the decline associated with [the relevant disease]"). Indeed, this Court recently considered an almost identical preamble and reached the same conclusion.

[8] Jazz's reliance on the quotation that the *TomTom* preamble "only states the intended use of the invention" is misleading. There was no dispute that the claim was "directed to a method for generating and updating travel-related data." *Id.* at 1324. Rather, the question in *TomTom* was simply whether the phrase "generating and updating data for use in" a system required the step of actually using the data. *Id.* at 1322-23. That differs from the issue here—whether "a method for treating . . . a patient in need thereof," requires treating a patient in need—particularly where the claims rely on that phrase for the antecedent basis of patient.

Novartis I at *2 (holding that "[t]he language of the preamble ('[a] method for treating relapsing remitting multiple sclerosis in a patient in need thereof') contemplates an efficacious purpose").

The remainder of the intrinsic record similarly supports an efficacious purpose. For instance, as in *Novartis I*, when the specification recites an efficacy problem that the invention is attempting to solve, such evidence supports "[t]he efficacious purpose set forth in the claims." *Id.* at *3 (relying on the specification's statement that "there is a significant unmet need for effective new therapies in MS, which limit or reduce the possible adverse events or side effects"). The Sustained Release specification similarly recites an efficacy problem the invention was attempting to address: "it is difficult to formulate a controlled release dosage form that ***maintains an effective concentration of the drug*** over a sustained period of time." Ex. B at 1:26-28 (emphasis added). This Court also recognized in *Novartis I* that distinguishing the prior art based on its lack of efficacy for the treated condition further supported an efficacious purpose requirement. *Id.* at *3. Just so here, as the Notice of Allowance for both Sustained Release Patents explains that they were allowed over a prior art reference because "[t]he prior art does not teach or suggest, however, a method of treating cataplexy or excessive daytime sleepiness associated with narcolepsy." Ex. D ('956 patent File History, December 18, 2020 Notice of Allowance) at 2; Ex. E ('931 patent File History, January 6, 2021 Notice of Allowance) at 2. If that portion of the claim has no substantive import, as Jazz now suggests, it could hardly form the basis of a difference from "[t]he prior art." Thus, not only are the preambles limiting, but they are specifically a limiting statement of the efficacious purpose of the invention.

The cases Jazz cites in arguing against an efficacious purpose are either inapposite or support Avadel.[9] Jazz relies on *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.* for the proposition that "no safety or efficacy [is] required where the claimed method steps 'are performed in the same way regardless whether or not the patient experiences a [certain measure of efficacy].'" *Supra* at 5 (quoting 246 F.3d 1368, 1375 (Fed. Cir. 2001)). Yet the claim term in that case, "for reducing hematologic toxicity," did not include the word "treating," and was part of a preamble that was found to be entirely non-limiting. *Id.* Thus, it is inapplicable to the question of whether a limiting preamble of "a method for treating . . . a patient in need thereof" requires an efficacious purpose.

Similarly, Jazz relies on *Novartis Pharms. Corp. v. Actavis, Inc.* (*Novartis II*), to argue that the "plain meaning of 'treating' is 'to ***attempt*** to cause a therapeutic improvement, without necessarily having assurance of what the outcome will be.'" *Supra* at 5 (quoting No. CV12-366-RGA-CJB, 2013 WL 6142747, at *11 (D. Del. Nov. 21, 2013)). That very quote shows that the plain and ordinary meaning of treating "treating" requires an efficacious purpose, just not a certainty of outcome.[10] Thus, if anything *Novartis II* supports Avadel's proposed construction.

---

[9] Many of the cases Jazz cites are from other districts and are distinguishable. For instance, in *Chiesi USA Inc. v. MSN Pharmaceuticals Inc.*, the issue was not whether the claims required efficacy at all, but rather whether treating was limited to attempts to "cure or heal" the disease, as opposed to those that "manage" it. No. CV19-18564, 2021 WL 4843806, at *4 (D.N.J. Oct. 18, 2021). *Celgene Corp. v. Hetero Labs Ltd.* is inapposite because the preamble containing the word "treating" was found to be entirely non-limiting and did not provide any antecedent basis like the instant claims. *See* No. CV17-3387 (ES) (MAH), 2020 WL 3249117, at *5-6 (D.N.J. June 16, 2020).

[10] Both *In re Ciprodex* and *Schering Corp. v. Mylan Pharmaceuticals, Inc.*, which Jazz cites, similarly reject the requirement that "treating" requires efficacy in every instance, but acknowledge that it is the goal of treatment. No. 15-cv-5756 (PGS)(DEA), 2017 WL 2784410, at *11 (D.N.J. June 27, 2017) (construing treating to mean "attempting to cause a therapeutic improvement in a human patient"); No. C.A. 09-6383 (JLL), 2011 WL 2446563, at *5 (D.N.J. June 15, 2011) ("To treat a disease does not imply that the progression of the disease will actually be slowed, arrested, or reversed, but the plain meaning of 'treatment' does imply a goal of achieving those results.").

Jazz also cites *United Therapeutics Corp. v. Liquidia Technologies, Inc*. for the proposition that "'[q]uestions of safety and efficacy in patent law have long fallen under the purview of the FDA,' and 'decline[d] to insert the FDA's responsibilities into claims by importing requirements where they do not recite such limitations.'" *Supra* at 3-4 (quoting 74 F.4th 1360, 1368-69 (Fed. Cir. 2023) (alterations in original). However, the claims there differed significantly from those here, requiring "treating pulmonary hypertension comprising administering ... a therapeutically effective single event dose of a formulation comprising treprostinil," *United Therapeutics*, 74 F.4th at 1368. The district court had already construed "therapeutically effective single event dose" to require "an improvement in a patient's hemodynamics," a construction that was not challenged on appeal. *Id.* at 1369. The Federal Circuit merely explained that when "[r]ead in context, the claim language 'treating pulmonary hypertension' does not import any additional efficacy limitations or any safety limitations" beyond those of a "therapeutically effective single event dose." *Id.* Here, the claims do not specify a "therapeutically effective" dose, as Jazz acknowledges, and Avadel's proposed construction commensurately does not require "an improvement." Thus, *United Therapeutics* is inapposite because Avadel's proposed construction merely recognizes that "treating" a patient involves administration for an "efficacious purpose."

c) Jazz's Reply Position

(1) The preambles are not limiting

Avadel argues that the preambles are limiting because "a patient in need thereof" allegedly provides antecedent basis for "the patient" in the body of the claims and "give[s] life and meaning to the purpose of the method." *Supra* at 8. Avadel is wrong on both counts.

The *Eli Lilly* case that Avadel relies upon did not look solely to "antecedent basis" to find the preamble limiting. Instead, *Eli Lilly* stated that "[w]hether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention

described in the patent." *Eli Lilly & Co.*, 8 F.4th at 1340. *Eli Lilly* then considered a term in the claims that is ***not*** present in Jazz's MoT Claims. Specifically, *Eli Lilly* found that the claim language "effective amount" provided support for the preambles being limiting. *Id.* at 1342-43. In the asserted MoT Claims, however, there is no "effective amount" claim limitation. Thus, the lack of any "effective amount" limitation in Jazz's MoT claims distinguishes them from the claims in *Eli Lilly*.

Next, Avadel tries to downplay the fact that the "in need thereof" language appears in Jazz's MoT Claims' preambles, as opposed to the body of the claims. Citing *Jansen* as alleged support for its "life and meaning" argument, Avadel claims that the Federal Circuit "explicitly rejected" the argument that the limiting nature of "in need thereof" does not take effect when it appears in the preamble versus the body of the claim. *Supra* at 8 n.7. But that argument was not made, and could not have been made; "in need thereof" appeared in the body of the claims, not the preamble, in *Jansen*. And *Jansen* "explicitly" found that "the claim preamble sets forth the objective of the method, and the ***body*** of the claim directs that the method be performed on someone '***in need***.'" *Jansen*, 342 F.3d at 1333 (emphasis added). The Federal Circuit then held that the "treating or preventing" language in the preamble, and the "in need" language in the body, "together . . . compel the claim construction arrived at by both the district court and this court." *Id.* No such connection appears between the preamble and the body in Jazz's MoT Claims.

Avadel next erects a straw-person—it claims that Jazz is arguing that efficacy is a requirement of its MoT Claims for some issues in the case, but not for others. *Supra* at 8-9. That is incorrect. Jazz has never taken the position that the preambles are limiting language that require efficacy. And notably, ***Avadel's experts agree***, arguing for invalidity without any mention of safety and efficacy. *See, e.g.*, Ex. 14 at ¶¶ 51-52 (silent on safety and efficacy, arguing anticipation

of all SR Patent claims, and stating that "[t]he preamble of claim 1 of the '488 patent [which contains no method language] is representative of the preambles for the Asserted Claims of the Sustained Release Patents"); Ex. 15 at ¶¶ 45-56, 103-113 (silent on safety and efficacy when arguing that prior art anticipates and renders obvious "[a] method of treating narcolepsy in a patient in need thereof, the method comprising," "administering a single daily dose to the patient," and "[t]he method of claim 1, wherein the administering promotes the patient to sleep for 6 to 8 hours").[11]

Finally, Avadel overlooks that, even if the "in need thereof" language is limiting, that does not result in the entire preamble being limiting. Instead, at most and consistent with *TomTom*, it provides the patient population to whom the claimed sustained release formulation is "deliver[ed]," nothing more.[12] *TomTom, Inc.*, 790 F.3d at 1323. Jazz does not "agree[] that the whole preamble must be construed as a single term" for purposes of determining whether it is limiting, as Avadel wrongly alleges. *Supra* at 9.

(2) The parties agree that the MoT Claims do not have an efficacy limitation

Avadel concedes for the first time that there is no efficacy requirement in the claims (acknowledging that "treating" does not require "a certainty of outcome" and that Avadel's construction "does not require 'an improvement'"). *Supra* at 11-12. Indeed, the cases Avadel cites support Jazz's position that, if the entire preamble is limiting, it only requires an ***attempt*** to cause an improvement in the conditions recited in the preamble. *See, e.g.*, *Manning v. Paradis*,

[11] Notably, Avadel's expert's opinions are "[t]o the extent that this preamble is limiting (i.e., acts as a claim limitation)" (Ex. 15 at ¶ 45), and "to the extent [the preamble] is limiting" (Ex. 14 at ¶ 52), evidencing that Avadel did not assert that the preambles were limiting.

[12] It certainly does not require efficacy. For example, *Eli Lilly* required the "effect[ing of] beneficial or desired results" because the claims also included the term "effective amount," which notably again is not a limitation of Jazz's MoT Claims. *See Eli Lilly*, 8 F.4th at 1342-43.

296 F.3d 1098, 1103 (Fed. Cir. 2002) ("The plain meaning of the word 'treat' requires that the invention of the count is used to seek ***or*** to achieve a therapeutic effect on the subject, rather than simply providing oxygen to the subject's heart.") (emphasis added).

The *Novartis* cases do not demand a different outcome. Instead, both Judge Stark and this Court construed the same phrase ("[a] method for treating Relapsing-Remitting multiple sclerosis in a subject in need thereof") to mean same thing ("a limiting statement of purpose"). *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043-LPS, D.I. 561 at 5 (D. Del. June 5, 2019)[13]; *Novartis Pharms. Corp. v. HEC Pharm Co.*, No. 20-133, 2023 WL 2810062, at *2-3 (D. Del. Apr. 6, 2023). That is ***not*** Avadel's proposed construction. Instead, Avadel injects "efficacious" before "purpose" in its proposed constructions. But Judge Stark held that "efficacy is not a limitation of the claims" and should not be "read[ ] into the claims," C.A. No. 18-1043-LPS, D.I. 561 at 9, and this Court noted that the "parties agree that the preamble . . . does not require actual efficacy," *Novartis*, 2023 WL 2810062, at *2.

Further, Judge Stark's construction was the subject of a written description dispute on appeal, and the Federal Circuit specifically recognized that "efficacy is not a requirement of the claims. The claims require only administration of a 0.5 mg/day dose for, *inter alia*, treatment purposes." *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362, 1371 (Fed. Cir. 2022), *opinion vacated on reh'g on other grounds*, 38 F.4th 1013 (Fed. Cir. 2022), *cert. denied sub nom. Novartis Pharms. Corp. v. HEC Pharm Co.*, 143 S. Ct. 1748 (2023). Jazz's construction is consistent with that recognition at the Federal Circuit—that there is no efficacy requirement in the claims. Thus, Jazz is not trying to read a negative limitation into the MoT Claims. Instead,

[13] Although not reflected in the case caption, it was the same parties (Novartis and HEC), disputing the same term, in both cases.

Jazz is trying to prevent Avadel from reading a non-existent efficacy limitation into the MoT Claims.[14]

Avadel's incredibly brief reference to the SR Patents' specification does not support its position either. Avadel points to a discussion of the formulation of controlled release dosage forms with effective concentrations (Ex. 2 at 1:26-28), *see supra* at 10, but Avadel does not address the arguments Jazz raised in its opening portion about the specification, including that, here, none of the SR MoT Claims recite effective concentrations as claim limitations, *see supra* at 5-6. This is a meaningful distinction, as noted for example by Judge Burke in *Novartis Pharmaceuticals Corporation v. Actavis, Incorporated.* There, Judge Burke rejected an efficacy requirement where the claims "do not recite methods of 'therapeutically treating' or 'effectively treating' diseases." No. 12-366, 2013 WL 6142747, at *9-11 (D. Del. Nov. 21, 2013). The outcome should be the same here.[15]

Finally, Avadel's reliance on the Examiner's notices of allowance for the SR MoT Claims also fails to support its position. *See supra* at 10. There is no mention of efficacy in those notices. *See* Exs. 4-5. Instead, as explained in Jazz's opening portion, the notices are focused on the sustained release formulations recited in the bodies of the SR MoT Claims. *See supra* at 6. In particular, the notices focus on how the composition and release of those formulations, compared to the formulations in the prior art Conte reference, is what formed "the basis of a difference from '[t]he prior art.'" *See supra* at 10; Exs. 4-5.

---

[14] Avadel appears to acknowledge that Jazz's other cited cases support that efficacy is not required by Jazz's MoT Claims. *See supra* at 11-12.

[15] Avadel's attempt to distinguish *United Therapeutics* only further supports Jazz. As Avadel recognizes, the efficacy required in those claims by the "therapeutically effective" dose means that the *United Therapeutics* claims "differed significantly from those here." *Supra* at 12. It in no way supports reading efficacy into "treating," nor would that be consistent with the case law Jazz has provided.

d) Avadel's Sur-Reply Position

(1) The Preambles Are Substantive Limitations

Setting aside what the preambles mean, they must mean ***something***. *Eli Lilly* held that a preamble is limiting where, as here, other claim terms refer back to it. *Supra* at 8. Jazz notes that the preamble in *Eli Lilly* explicitly required an "effective amount," but the point is that the Federal Circuit gave the preamble meaning, not the specifics of what the preamble meant. 8 F.4th at 1340. Here, "the patient" in the claims refers to "a patient in need" in the preambles. The preambles are therefore limitations, just as in *Lilly*. Jazz agreed when it served its infringement contentions.[16] *Supra* at 8 (citing Ex. C at 108, 178, 207, and 214).

Jazz's efforts to distinguish *Jansen* similarly fail. *Supra* at 13. Jazz notes that in *Jansen*, the relevant language was split between the preamble and the body, 342 F.3d at 1333, but that is also true here. Jazz is also wrong that there is no connection here between the preamble and body language: without the preamble, the "patient" in Jazz's claims could be suffering from *any* ailment, whereas with the preamble and the body together, the claim has meaning and is directed to giving a narcolepsy drug to a patient suffering from cataplexy or excessive daytime sleepiness associated with narcolepsy.

Finally, this Court can disregard Jazz's new argument that only a portion of the preamble is limiting, and that the limiting portion only defines a patient population. *First*, as noted above, it is only when the full preamble is given meaning that the claim makes sense as being about

[16] Avadel's experts did not agree that the preambles are non-limiting. *Supra* at 14 n.11. They included the "to the extent" language because the Court had not ruled on the question. And Avadel's clinical experts addressed safety and efficacy in reports that ***Jazz omits***. The reports that Jazz attached were from Avadel's formulation experts, not clinicians. *See, e.g.*,, Ex. H. (Scharf Opening Report) at ¶ 36 ("[T]o make the judgment that a sodium oxybate formulation could be safely and effectively administered . . . I would need to see that the formulation would achieve blood levels that would maintain sleep . . .").

treating narcolepsy patients. *Second*, in its opening brief, Jazz proposed an alternative construction for the entire preamble. A reply brief is too late for a new claim construction argument. *See* D. Del. LR 7.1.3(c)(2).

(2) A "method for treating . . . a patient in need thereof" Is a Statement of Efficacious Purpose

Jazz is wrong that the parties agree "there is no efficacy requirement in the claims." *Supra* at 14. If the parties agree on anything, it is that treating a disease does not guarantee a cure. That does not make "treating" meaningless. As this Court recognized, the purpose of the claimed method is to treat. *Novartis Pharms. Corp. v. HEC Pharm Co.*, No. C.A. 20-133-GBW, 2023 WL 2810062, at *2 (D. Del. Apr. 6, 2023) (*Novartis I*) ("[t]he language of the preamble ('[a] method for treating relapsing remitting multiple sclerosis in a patient in need thereof') contemplates an efficacious purpose"); *see also Novartis Pharms. Corp. v. Actavis, Inc.*, No. C.A. 12-366-RGA-CJB, 2013 WL 6142747, at *11 (D. Del. Nov. 21, 2013) (*Novartis II*) (treating requires an "attempt to cause a therapeutic improvement.").

Jazz objects to the word "efficacious" in Avadel's construction, but this Court recently construed a nearly identical preamble as a "limiting statement of purpose." *Novartis I* at *2. While the final construction did not include "efficacious," the Court rejected the proposal of a "[l]imiting statement of purpose *that does not require efficacy*." *Id.* And the Court's opinion repeatedly refers to the claims' "efficacious purpose." *Id.* at 2-3. Here, it makes sense to be explicit that the preamble requires an efficacious purpose to avoid further disputes.

Jazz's citation to *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043-LPS, D.I. 561 at 5 (D. Del. June 5, 2019) (*Novartis III*),[17] confirms that preambles like those here

[17] Throughout briefing, the parties cited *Novartis I*, a 2023 decision by this Court, and *Novartis II*, a 2013 decision by Magistrate Burke. Jazz's reply cites to a third, 2019 opinion by Judge Stark.

are limiting. *Id.* at 8. Jazz ignores that and focuses on the court's rejection of a secondary argument "that the claims also 'require an *actual* effect.'" *Id.* As for the Federal Circuit appeal on written description issues, that, too, dealt with efforts to read into the claims a requirement that a particular dose actually work. 21 F.4th 1362, 1371 (Fed. Cir. 2022). But Avadel is not proposing that the administered treatment must actually work. And Jazz omits that there had been a finding at trial, not appealed, that "the [treatment] purpose limitations are adequately described." *Id.*

Jazz also wrongly insists that the specification's discussion of effective concentrations is irrelevant because the claims do not use the word "concentration." *Supra* at 16. There is no such rule permitting portions of the specification to be ignored. And as this Court has previously recognized, where the specification sets forth an "efficacious purpose," that is further evidence in support of a such a construction. *Novartis I* at *2. That is the case here. The notices of allowance support Avadel's position because they distinguish prior art based on the condition being treated. *Novartis I*; Ex. D ('956 patent File History, December 18, 2020 Notice of Allowance) at 2 (allowing the claims because "[t]he prior art does not teach or suggest, however, a method of treating cataplexy or excessive daytime sleepiness associated with narcolepsy"); Ex. E ('931 patent File History, January 6, 2021 Notice of Allowance) at 2 (same).

B. The '079 Patent Method of Treatment Claims

1. Preambles

Claim Term	Jazz's Proposal	Avadel's Proposal
"A method of treating [narcolepsy/cataplexy or excessive daytime sleepiness associated with narcolepsy] in a patient in need thereof"	not limiting; if limiting, then the plain and ordinary meaning of "treating": an attempt to cause an improvement, without any requirement of efficacy or safety[18]	A limiting statement of efficacious purpose

a) Jazz's Opening Position

Avadel attempts to import an efficacy limitation based on: (1) the preambles; (2) "a single daily dose" limitation; and (3) for claims 5 and 14, the "wherein" clause. Each attempt lacks merit.

Claims: The same analysis for the SR MoT Claims applies here. The only difference is that, for the '079 MoT Claims, more than just delivery of the formulation is required. For the '079 MoT Claims, one must "open[] a sachet," "mix[] the formulation with water," and then "orally administer[] the mixture." Like the SR MoT Claims, however, the steps are performed the same way regardless of whether there is an efficacious result.

Specification: The '079 specification also uses the plain meaning of "treatment" and "treating"—i.e., not requiring efficacy.[19] *See, e.g.*, Ex. 3 at 1:37-40, 21:16-19. Additionally, the claims do not require any "therapeutically effective amounts." *Compare* Ex. 3 at 4:4-29 (describing embodiments "to maintain the blood level of GHB" at certain concentrations for sleep) *with* Claims (not claiming those blood levels).

---

[18] *See supra* at 3, n.5.

[19] The published application for the SR Patents (US 2012/0076865, Ex. 6), which contains the same disclosures as the SR specification, is also "incorporated by reference [in the '079 specification] in [its] entiret[y] for all purposes." Ex. 3 at 2:61-67. This provides further support for the plain meaning of "treating."

File History: Avadel cannot cite any clear reliance on the preambles in the '079 file history to overcome any rejection. Instead, Jazz argued for patentability because "the prior art as a whole teaches against using a solid oxybate formulation in a sachet, as required by the present claims." Ex. 7 at 10. Like the SR MoT Claims, this further supports Jazz's position.

b) Avadel's Answering Position

The preambles of the '079 Patent's claims are similarly substantive limitations of efficacious purpose. The claim language itself, "[a] method for treating . . . in a patient in need thereof," is virtually identical, and thus supports an efficacious purpose as set forth *supra* at Section II.

Moreover, the intrinsic record supports Avadel's proposed construction. Indeed, the '079 patent describes efficacy as the object of its invention. Ex. F ('079 patent) at 4:4-6 (stating that the "object of the invention is to maintain the concentration of GHB in the blood at levels sufficient to promote sleep for up to 8, 7, 6, or 5 hours"); *id.* at 4:6-13 (stating that the "object of the invention" further includes "maintain[ing] the blood level of GHB from about 10 mg/L to about 20 mg/L for up to 8, 7, 6, or 5 hours" and "ensur[ing] that the sleep inducing effects of GHB do not remain for longer than the above periods as it would compromise a patient's ability to perform normal day to day activities"). Such statements are explicit support for requiring efficacious purpose. *318 Patent Infringement Litig.*, 578 F. Supp. 2d at 725.

Further, Jazz relied on the preambles' recitation of treating an oxybate-treatable condition to distinguish the prior art. Ex. G ('079 patent File History, May 20, 2021 Remarks) at 8 (distinguishing the invention from the prior art because the prior art did not "alone or in combination, teach or suggest the … sachet's once daily administration to treat an oxybate-treatable condition").

c) Jazz's Reply Position

The same analysis as applied above for the SR MoT Claims applies here. Further, Avadel's arguments specific to the '079 specification and file history also fail. For the specification, Avadel again does not respond to the arguments raised in Jazz's opening portion, but instead focuses on blood concentrations in the specification (Ex. 3 at 4:4-13) in an attempt to support efficacy. *Supra* at 21. But Jazz already noted in its opening portion how those blood concentrations, although they could have been, are ***not recited*** in the '079 MoT Claims. *See supra* at 20-21, *infra* at 26-27. And the portion of the file history that Avadel points to, which Jazz also addressed in its opening portion, focuses on Jazz distinguishing its claimed sachet dosage form from other dosage forms (i.e., liquid formulations) in the prior art, including by arguing how the properties of GHB (e.g., hygroscopicity) would teach away from using a sachet. Ex. 7 at 7-10. Indeed, like the SR MoT Claims' file history, efficacy is not mentioned in the portion of the file history that Avadel cites here.

d) Avadel's Sur-Reply Position

Jazz makes two arguments specific to the '079 patent. First, Jazz disputes Avadel's reliance on the disclosure of effective blood levels because they are not recited in the claims. *Supra* at 22. But those statements from the specification are relevant for the same reason discussed above: they highlight that the "object of the invention" is to "promote sleep," which has been held relevant to construing the purpose of the invention. *Supra* at 21 (citing *In re 318 Patent Infringement Litig.*, 578 F. Supp. 2d 711 (D. Del. 2008)).

Second, Jazz argues that Avadel incorrectly relies on the prosecution history because Jazz was "distinguishing its claimed *sachet* dosage forms from other dosage forms." *Supra* at 22. But Jazz also distinguished the prior art because it purportedly did not show treatment of patients: Per Jazz, none of the prior art "alone or in combination, teach or suggest the claimed method of

administering a solid oxybate formulation using a sachet, ***let alone a sachet's once daily administration to treat an oxybate-treatable condition***." Ex. G ('079 patent File History, May 20, 2021 Remarks) at 8.

2. "a single daily dose"

Claim Term	Jazz's Proposal	Avadel's Proposal
"a single daily dose"	No construction required; if required, then "one and only one dose per day," without any requirement of efficacy or safety[20]	"a single daily dose effective to treat [narcolepsy/cataplexy or EDS associated with narcolepsy]"

a) Jazz's Opening Position

Unlike in *United Therapeutics*, the claims here do ***not*** recite a "***therapeutically effective*** single dose." 74 F.4th at 1369 (emphasis added). Instead, the claims recite "administering a single daily dose to the patient, the single daily dose comprising an amount of oxybate equivalent to from 4.0 g to 12.0 g of sodium oxybate." Dosage amounts within the claims do not compel an efficacious result. *See, e.g.*, *Bristol-Myers*, 246 F.3d at 1375 ("The express dosage amounts are material claim limitations; the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim."); *Celgene*, 2020 WL 3249117, at *5 (no safety or efficacy requirement despite dosage amounts in claims). The claims only require "a single daily dose," as opposed to multiple daily doses. As this Court has previously held, "[s]ingle means 'one and only one.'" D.I. 229 at 19. This is consistent with the specification's distinguishing of "once-a-day dosing" from "tak[ing] multiple doses per day." *See* Ex. 3 at 6:42-49. The plain meaning should apply. To the extent that Avadel relies on Jazz's argument during prosecution that the "presently-claimed methods provide therapeutic effectiveness through once-

[20] *See supra* at 3, n.5.

daily administration" (Ex. 7 at 12), that merely describes "a 'result of administering' the claimed invention," which does not transform the result into a claim limitation. *Celgene*, 2020 WL 3249117, at *7.

b) Avadel's Answering Position

The "single daily dose" limitation of claims 1 and 10 of the '079 patent also requires an efficacious purpose. As discussed above, both the specification and the prosecution history tie once-daily dosing to a treatment effective with such a dosing regimen. *See supra* at 21.

Indeed, Jazz's reliance upon therapeutic efficacy "to define the claimed methods and distinguish them from the prior art" demonstrates that the condition was "material to patentability and thus limiting." *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370, 1376 (Fed. Cir. 2019). The prosecution history shows that Jazz relied on the efficacy of a single daily dose to respond to the Examiner's rejections. *See* Ex. G at 11 (Jazz distinguishing its pending claims from the prior art because "when the present application was filed, it was understood in the art that oxybate ***required twice-daily administration to be therapeutically effective***") (emphasis added); *id*. at 12 (Jazz distinguishing its pending claims from the prior art because "[i]n contrast, ***the presently-claimed methods provide therapeutic effectiveness through once-daily administration***") (emphasis added).

Jazz's reliance on *Bristol-Myers Squibb* and *Celgene* is again misplaced. In *Bristol-Myers Squibb*, the court found the term "an antineoplastically effective amount" non-limiting in part because the patentee added the term voluntarily after the examiner indicated that the claims were allowable, and that "unsolicited assertions of patentability made during prosecution do not create a material claim limitation . . . ." 246 F.3d at 1375. Similarly, in *Celgene*, the court held that the patentee failed to establish that the prosecution history "demonstrates that the patentee intended efficacy to be a 'necessary feature' of the claimed methods." 2020 WL 3249117, at *7. In contrast,

here, the prosecution history makes clear that Jazz understood its invention to "provide therapeutic effectiveness through once daily administration." *See* Ex. G at 8, 11, 12.

c) Jazz's Reply Position

For the reasons set forth in Jazz's opening portion, the "single daily dose" limitation does not support reading an efficacy limitation into the '079 MoT Claims. *See supra* at 23-24. Avadel's reliance on *Allergan* does nothing to change that conclusion. Avadel argues that Jazz relied on the "single daily dose" limitation to distinguish the prior art. *Supra* at 24. But Avadel ignores the full context of Jazz's argument, which specifically relied upon, like the other portions of the '079 patent's file history, the packaging of such a single daily dose in a sachet containing both immediate release and controlled release particles. *See* Ex. 7 at 11-12. Moreover, Jazz's comments in the file history were, much like in *Bristol-Myers Squibb*, voluntarily made and not addressing a rejection made by the Examiner based on the "single daily dose" limitation. *See Bristol-Myers Squibb Co.*, 246 F.3d at 1375 ("[U]nsolicited assertions of patentability made during prosecution do not create a material claim limitation . . . ."); Ex. 7 at 11-12 (discussing the "single daily dose" limitation under the heading "Examiner's Rejection Does Not Address All the Claim Elements").

Not only is a therapeutically effective single daily dose not a material limitation of the '079 MoT Claims, it is not even a ***recited*** limitation of the '079 MoT Claims. Indeed, unlike the claims in *United Therapeutics*, the '079 MoT Claims recite a "single daily dose" ***not*** a "therapeutically effective single dose." *See United Therapeutics Corp.*, 74 F.4th at 1369 (Fed. Cir. 2023). That distinction, as seen for example in *Novartis Pharmaceuticals Corporation v. Actavis, Incorporated* discussed above, is a meaningful difference.

d) Avadel's Sur-Reply Position

First, Jazz did far more than make voluntary statements about the prior art. Jazz explained during prosecution that "none of the ***cited references*** suggests the claim-recited single daily administration of a solid oxybate formulation dispensed from a sachet to treat an oxybate-treatable condition." Ex. G ('079 patent File History, May 20, 2021 Remarks) at 11-12. Indeed, Jazz made clear that "[i]n contrast, ***the presently-claimed methods*** provide ***therapeutic effectiveness*** through once-daily administration…." *Id.* at 12.

Second, Avadel agrees that in *United Therapeutic*, the Court construed the term "therapeutically effective single event dose" to mean "an improvement in a patient's hemodynamics." 74 F.4th 1360 at 1370. But Avadel's proposed construction does not require actual improvement. *Supra* at 12. *United Therapeutics* is therefore irrelevant, as the parties appear to agree.

3. Claims 5 and 14's "wherein" clause

Claim Term	Jazz's Proposal	Avadel's Proposal
"wherein the administering promotes the patient to sleep for 6 to 8 hours"	Statement of an aspirational or intended result without any requirement of efficacy or safety[21]	The wherein clause is limiting

a) Jazz's Opening Position

Wherein clauses are not limiting when they state aspirational or intended results and were not relied upon in the file history to distinguish the claimed inventions from the prior art. *See L'Oreal USA v. Olaplex, Inc.*, 844 F. App'x 308, 324 (Fed. Cir. 2021); *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370, 1376 (Fed. Cir. 2019). The "wherein" clause here satisfies those

[21] *See supra* at 3, n.5.

requirements. This is consistent with the specification's focus on blood levels (***not*** recited in the '079 MoT Claims) for attempting to achieve the aspirational or intended result of promoting sleep for 6 to 8 hours. *See* Ex. 3 at 4:4-29. The specification, as dictionaries do, also distinguishes "promot[ing]" sleep (aspirational in that it is encouraging something to take place) from "inducing" sleep (causing something to happen). *See id.*; *see also* Exs. 8-10. The claims recite "promotes" not "induces."

b) Avadel's Answering Position

The wherein clauses of claims 5 and 14 are limiting because each wherein clause is the ***only additional limitation*** in those claims. Rendering them surplusage would leave the claim scope identical to the claims from which they depend. The Federal Circuit has held that where dependent claims "state specific requirements" and "that is all they do," treating those "limitations as [having] no legal effect would be to interpret each of [those] dependent claims as entirely a nullity." *See L'Oréal USA, Inc. v. Olaplex, Inc.*, 844 F. App'x 308, 324 (Fed. Cir. 2021) (holding that in "requiring specific decreases (*e.g.*, 5%, 10%, 20%, 40%, 50%) in hair breakage, they state specific requirements rather than a general purpose or aspirational result") (internal quotation omitted). Jazz does not, and cannot, dispute that these claims are dependent claims or that the addition of the "wherein" clauses "is all [the dependent claims] do." *See id.*; *see also* Ex. F at 4:4-6 (explaining that the invention "promote[s] sleep for up to ***8, 7, 6, or 5 hours***") (emphasis added).

Nevertheless, Jazz contends that the "wherein" clauses of dependent claims 5 and 14 of the '079 patent are not limiting because they state aspirational or intended results. Jazz's argument ignores the plain language of dependent claims 5 and 14.[22] *Supra* at 26-27. Claims 5 and 14 of

[22] Jazz improperly characterizes the '079 patent specification as "promoting sleep for 6 to 8 hours." *Supra* at 27. In fact, the specification discloses "promot[ing] sleep for up to 8, 7, 6, or 5 hours." (continued…)

the '079 patent contain the specific requirement of promoting patients "to sleep for ***6 to 8 hours***," and contain no other limitation apart from the "wherein" clause. In its Final Infringement Contentions, Jazz took the position that "Avadel's NDA Product will literally meet" the limitations of these claims because it will "allow [] patients at least six hours of continuous and improved sleep" and because "plasma GHB concentration [will be] maintained throughout the night, as well as gradual[ly] decline to lowest levels by 8-10 hours after dosing." Ex. C at 212, 219 (first alteration in original). Jazz now takes the position that the "specification, as dictionaries do, also distinguishes 'promot[ing] sleep (aspirational in that it is encouraging something to take place) from 'inducing' sleep (causing something to happen)," and that the dependent claims use the term "promotes" rather than "induces." *Supra* at 27.[23] However, the '079 patent specification does not distinguish between "promotes" and "induces." *See* Ex. F at 4:10-13 ("the sleep ***inducing*** effects of GHB do not remain for longer than the above [8, 7, 6, or 5 hour periods] as it would compromise a patient's ability to perform normal day to day activities . . . ."). Jazz's reliance on an unrelated term in the specification to distinguish its use of "promotes" in dependent claims 5 and 14 is therefore unavailing. As Jazz recognized when it finalized its contentions, the "wherein" clauses are the ***only*** additional limitations to those claims. They must mean ***something***.

Ex. F at 4:4-6. Thus, Jazz affirmatively chose the narrower range of 6 to 8 hours for dependent claims 5 and 14.

[23] As an initial matter, Jazz's paraphrased definition of "promot[ing]" appears to be "encouraging something to take place." *Supra* at 27. However, each of the three dictionary definitions that Jazz cites does not apply the aspirational meaning that Jazz purports it does. *See, e.g.*, Ex. 8 (defining "promote" as "to encourage ***or enable*** something to take place") (emphasis added); Ex. 9 (defining "promote" as "to help something to happen or develop"); Ex. 10 (defining promote as "to help something develop and be successful").

c) Jazz's Reply Position

Avadel argues that the "wherein" clauses are limiting and "must mean ***something***," but neither Avadel's construction nor its opposition explicitly say what that "***something***" is. *See supra* at 28. Jazz's construction, on the other hand, is reflective of the plain and ordinary meaning of the plain English word "promotes": an aspirational or intended result without any requirement of efficacy or safety. Avadel, while not providing any dictionary definitions of its own, attempts to imply that the dictionary definitions that Jazz provided for "promotes" mean that an actual result must occur. *Supra* at 28 n.23. But enabling or helping something to happen, which falls within the definition of "promotes," does not guarantee that the result will actually occur. The definitions for "induce," on the other hand, do guarantee that the result will actually occur. *See* Ex. 8 (defining "induce" as "to cause something to happen"); Ex. 9 (defining "induce" as "to cause . . . *drugs which induce sleep*"); Ex. 10 (defining "induce" as "[t]o cause a particular physical condition: *This drug may induce drowsiness*."). Again, Jazz chose to claim "promotes," not "induces." That distinction matters, and to the extent that Avadel's position is—although it is not recited in Avadel's proposed construction—that "promotes" means the same thing as "induces," Avadel is wrong.

d) Avadel's Sur-Reply Position

Jazz, for the first time in reply, argues that "neither Avadel's construction nor its opposition" explain what claim 5 and 14's wherein clauses mean. *Supra* at 29. Avadel does not believe that the terms require any clarification beyond their plain and ordinary meaning, and Jazz's arguments regarding the meaning of "promotes" and "induce" are beside the point. The only issue is Jazz's assertion that these clauses are "not limiting," which would result in claims 5 and 14 having the same scope as their corresponding independent claims. *Supra* at 26. This is plainly wrong.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
Nicholas A. LoCastro
Krista M. Rycroft
Quentin Jorgensen
Catherine T. Mattes
Abigail DeMasi
Raymond N. Nimrod
Ellyde R. Thompson
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

Alexandra Kim
QUINN EMANUEL URQUHART & SULLIVAN, LLP
111 Huntington Ave., Suite 520
Boston, MA 02199
(617) 712-7100

Christopher D. Porter
Elizabeth M. Devaney
QUINN EMANUEL URQUHART & SULLIVAN, LLP

MCCARTER & ENGLISH LLP

/s/ Daniel M. Silver

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

OF COUNSEL:

Kenneth G. Schuler
Marc N. Zubick
Alex Grabowski
Sarah W. Wang
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700
kenneth.schuler@lw.com
marc.zubick@lw.com
alex.grabowski@lw.com
sarah.wang@lw.com

Herman Yue
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020
(212) 906-1200
Herman.Yue@lw.com

Audra M. Sawyer
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, D.C. 20004
(202) 637-2200
Audra.sawyer@lw.com

Daralyn J. Durie
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105

Pennzoil Place
711 Louisiana Street, Suite 500
Houston, TX 77002
(713) 221-7000

Attorneys for Plaintiffs
Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland Limited

(415) 568-6034
ddurie@mofo.com

Kira A. Davis
Katherine E. McNutt
MORRISON & FOERSTER LLP
707 Wilshire Boulevard
Los Angeles, CA 90017
(213) 892-5200
kiradavis@mofo.com
kmcnutt@mofo.com

Counsel for Defendant
Avadel CNS Pharmaceuticals LLC

October 10, 2023